

CLAIMS

1 A method for purifying albumin comprising a step of submitting an aqueous albumin solution, with a concentration of 15 g/L to 80 g/L and a pH not lower than 7, to a nanofiltration in a temperature range of 15°C to 55°C.

2. A method according to Claim 1, characterised in
10 that the nanofiltration is carried out on qualified filters having porosities of at least 13 nm.

3. A method according to one of Claims 1 and 2, characterised in that the pH of the aqueous albumin
15 solution is in the range of 7.8 to 11.5, and preferably, of 9 to 10.5.

4. A method according to any of Claims 1 to 3, characterised in that it further comprises a step of
20 adding a pharmaceutically acceptable salt or salt mixture to the aqueous albumin solution to provide a solution with a ionic strength in the range of 0.01 to 0.55.

5. A method according to Claim 4, characterised in
25 that the pharmaceutically acceptable salt is a salt of an alkali metal.

6. A method according to Claim 5, characterised in that the salt of an alkali metal is sodium chloride
30 present in an amount imparting to the albumin solution an ionic strength of 0.15.

7. A method according to any of Claims 1 to 6, characterised in that the concentration of the aqueous albumin solution is in the range of 40 g/L to 60 g/L.

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8. A method according to any of Claims 1 to 7, characterised in that the temperature of the aqueous albumin solution is between 30°C and 55°C.

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9. A method according to any of Claims 1 to 8, characterised in that the nanofiltration of the aqueous albumin solution is carried out in two successive steps on two filters with decreasing porosities, respectively.

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10. A method according to Claim 9, characterised in that the two successive nanofiltration steps are carried out on filters with porosities of 23 to 50 nm and 15 or 20 nm, respectively.

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11. A method according to any of Claims 1 to 10, characterised in that it is implemented with regenerated cellulose filters of 15 nm having a surface area of 0,01 m², at a pressure not exceeding 1 bar.

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12. A method according to Claim 11, characterised in that the pressure is in the range of 0.2 to 0.8 bar.

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13. A method according to any of Claims 1 to 12, characterised in that the albumin is obtained by ethanol extraction and by purification by ion-exchange or affinity chromatography.

14. A method according to any of Claims 1 to 13, characterised in that it comprises a subsequent step of processing the aqueous albumin solution to make it
5 suitable to a therapeutic use.

15. A virally safe aqueous albumin solution obtainable by implementing the method according to any of Claims 1 to 14, in which the transport and binding sites
10 of therapeutically active ingredients are available in the albumin.

16. An aqueous albumin solution according to Claim 15, characterised in that it contains at most 1%
15 albumin polymers with a size smaller than 100 nm.

17. An aqueous albumin solution according to Claim 15 or 16, characterised in that it contains at most 1% albumin polymers with a size smaller than 20 nm.
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18. An albumin composition for therapeutic use obtained by a process according to Claim 14, for making an aqueous albumin solution according to any of Claims 15 to 17, suitable to a clinical use.
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19. The use of an albumin composition for therapeutic use according to Claim 18, for the stabilisation of at least one member selected from the group consisting of proteins in low concentrations and
30 with high specific activities, specific immunoglobulins,

monoclonal antibodies, vaccines, allergens, cytokines and peptidic hormones.

20. The use according to Claim 19, characterised in
5 that the proteins are factor VIII or von Willebrand factor, and their recombinant equivalents.

21. The use of an albumin composition for therapeutic use according to Claim 18, for the transport
10 and binding of therapeutically active ingredients.

22. The use of an albumin composition for therapeutic use according to Claim 18, as an excipient for an incubation medium for *in-vitro* fertilisation of
15 human oocytes.

23. The use of an albumin composition for therapeutic use according to Claim 18, as a control standard protein.